EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO PLAINTIFFS: Joy Essman Case No. 2:12-cv-00277 Christine Wiltgen Case No. 2:12-cv-01216 Shirley Walker Case No. 2:12-cv-00873 Julie Wroble Case No. 2:12-cv-00883 Nancy Jo Williams Case No. 2:12-cv-00511	

The deposition of GREGORY BALES, M.D. taken before Pauline M. Vargo, an Illinois Certified Shorthand Reporter, C.S.R. No. 84-1573, at the law offices of Drinker, Biddle & Reath, 191 North Wacker Drive, Suite 3700, Chicago, Illinois, on April 1, 2016, at 8:02 a.m.

MR. MORIARTY: Objection.

A. Yes, I believe my opinions are objective. They are opinions to my best ability to give an opinion based on my own training and to my best degree of medical certainty, if you will.

Q. And are your opinions unbiased?

MR. MORIARTY: Objection. Go ahead.

A. I think my opinions are unbiased.

Q. When you prepared -- did you prepare the report yourself?

A. I did.

Q. And how did you decide what to include and what not to include in your report?

MR. MORIARTY: Objection. Go ahead.

A. Well, as you can guess, you know, there is a voluminous amount of information that can go into a report like this and there is, you know, years and years of documents, scientific papers, research articles, journal articles and abstracts, et cetera. So, you sort of pick and choose and you try to get a broad array of Level 1 evidence that reflects good science. That's what I try to include.

Q. Did you receive materials from defense

BY MS. THOMPSON:

Q. This is an e-mail exchange about Prolift Users Forum from 2006. Did you participate in the Chicago Prolift Users Forum, to your memory?

A. Yeah, again, I apologize, my memory fails me on some of these things, but this was ten years ago. If it says I was at a forum one evening, then I guess I was, if my name is on this. But as I said, I really, I apologize, I can't remember ten years ago being part of this.

Q. When did you start using Prolift?

A. Probably about 2006, would be my best guess. I think it came online end of 2005.

Q. And if you did participate in this forum, that would be something that you would expect to be paid for by Ethicon, right?

MR. MORIARTY: Objection.

A. No, not necessarily. I mean, sometimes you participate in things because you wanted to get an opportunity to listen to other of your colleagues and other experts, and so I wouldn't necessarily expect to be paid, although oftentimes if you participate in things like this you would be paid.

Gynemesh, a piece of mesh used transvaginally.

MR. MORIARTY: You mean Gynemesh PS?

MS. THOMPSON: Gynemesh PS.

A. Are you asking me if I'm going to offer opinions or you would like opinions?

Q. No. Do you intend to offer opinions on Gynemesh PS?

A. I think I'm here to answer your questions today, which I will do to the best of my ability; and I'm certainly happy to answer and offer opinions on Gynemesh PS, which I'm familiar with.

Q. The Prolift devices?

A. Correct.

Q. Prolift+M?

A. Correct.

Q. Prosima?

A. I've never used Prosima. I won't be able to tell you very much about Prosima. I'm familiar with it, but never personally had any experience using it myself.

Q. And I didn't notice any opinions regarding Prosima in your report, so can we assume

that you will not be offering opinions on the Prosima device?

A. I won't, especially if you don't ask anything more about it, so why don't you cross it out.

Q. Thanks. I will cross it out.

A. Perfect.

Q. So with the products that we just mentioned, is it your opinion generally that each of these products is safe and effective?

A. That would be my opinion.

Q. And is it your opinion generally that each of these products offer advantages over native tissue repairs?

A. Well, they may offer some advantages, and I think we would have to clarify more specifically what we are talking about. I think that's a little bit too broad for me to just say I agree.

Q. And it was meant as a broad question. Obviously there will be specific instances, but in general, do the products offer advantages in your opinion over native tissue repairs?

A. I think for certain things they offer

breakdown would be probably 50 percent anterior Prolift, probably 45 percent total Prolift and a very smaller -- a much smaller percentage, 5 percent or less of the posterior Prolift.

Q. Have you published any peer-reviewed articles regarding using vaginal mesh for prolapse repairs?

A. Yes.

Q. What are those articles?

MR. MORIARTY: Objection.

A. Again, I mean, I think my CV -- do we have my CV here? I would have to show you. I don't remember the exact citation.

Q. Did you bring your CV?

A. I don't think I have a copy of my CV.

MR. MORIARTY: We produced it with the report and reliance list.

BY MS. THOMPSON:

Q. Okay. And do you treat mesh complications in your practice?

A. Absolutely. More complications than I care to.

Q. What are the most common mesh complications that you treat in your practice?

certainly seen pictures of the histologic presentations, and yes, I'm sure I have been in our pathology department at least a couple times and looked at some of these things. But, you know, it will be very difficult for me to describe the histologic appearance.

Q. So you would not consider yourself an expert in pathology?

A. I'm very knowledgeable about pathology, but I'm certainly not an expert and be able to describe the specific pathologic features that a pathologist, a board-certified pathologist would be able to do.

Q. Are you an expert in regulatory affairs?

A. That's such a broad thing, what regulatory affairs are, that again I guess I can't say I'm any kind of expert in regulatory affairs. I'm not sure even what that means.

Q. How about industry standards for warnings?

MR. MORIARTY: Objection, form.

A. So, an expert in industry, you are asking me if I'm an expert in industry standards of warnings.

So, again, I'm not -- I'm not aware of what those standards may be, so I guess I'm not an expert in it.

Q. We are going to go through your report. I'm going to ask you some questions about some of your opinions contained in the report. If you want to follow along, you are welcome to.

On Page 3 --

A. Can I just -- let me make sure I'm just working off the same copy. You said you gave it that. Was that Exhibit 2? Was it Exhibit 2?

Q. Exhibit 2, correct.

A. Can I have it just to make sure? Go ahead. Thank you.

Q. At the bottom of Page 3 you start out talking about sacrocolpopexy and then you also talk about uterosacral ligament suspensions and sacrospinous ligament fixations. Do you perform either of those procedures?

A. Yes.

Q. When was the last time you performed either one and which one?

A. A long time ago, a number of years ago, five years ago.

then say but I want to get started using it. So that's why, again, it is hard for me to interpret this.

Q. Was there any efficacy data when you began using that Prolift device in 2006?

A. There is never -- any new procedure we do, there is never any real good efficacy data on any new procedure.

Q. I want to go over some of the literature on the colporrhaphy and the efficacy, and I'm using -- I'm going to start with the Weber article that you cited in your report; and you are aware, Dr. Bales, that the Weber article from 2001 was re-analyzed with modern definitions of prolapse and success by Chmielewski, correct?

A. Yes.

Q. I'm curious why you cited the 2001 Weber article rather than the 2011.

A. So, I guess if that's a question, again, it's impossible to cite every article that's out there, so I picked certain ones.

MS. THOMPSON: And if you could mark this as Exhibit No. 8. I just have two copies of this, sorry.

(Bales Exhibit 8 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper, Dr. Bales?

A. Yes.

Q. And let's just go to the conclusions, and could you read the last paragraph for us.

A. Would you like me to read the entire last paragraph?

Q. Um-hmm?

A. Starting "In conclusion"?

Q. Um-hmm.

A. "In conclusion, this study provides further evidence that success after prolapse surgery depends heavily on the criteria that are used to define treatment success. In the frequently cited study by Weber, et al., when strict anatomic criteria were used, success was low. However, when contemporary, clinically relevant criteria for success were used, treatment success was considerably better, with only 11 percent of subjects experiencing anatomic recurrence beyond the hymen, 5 percent of subjects

experiencing symptomatic recurrence, and no subjects requiring surgery for recurrence or complications at one year.

"Given this and the excellent safety profile of traditional vaginal prolapse surgery, we conclude that anterior colporrhaphy that is performed in conjunction with other native tissue repairs is appropriate as a primary treatment of symptomatic anterior vaginal prolapse."

Q. And my question is, why did you cite the Weber paper in 2001 when this paper is more recent and more authoritative?

MR. MORIARTY: Objection, form and asked and answered. Go ahead.

Q. Well, let me just say, is your -- is your -- the reason that you didn't use this paper is you just can't cite everything? I think that was your answer before. Is that it --

A. Yeah --

Q. -- why you chose the old paper?

A. Yeah, I apologize. I chose -- I tried to choose a appropriate synopsis of a variety of different things. I'm sure there are other papers that I missed that might be more current or what

have you. But again, there is a lot of literature that's out there. I had to cite certain things.

Q. And you will certainly agree with me that a 5 percent symptomatic recurrence and no subjects requiring additional surgery is very different from the recurrence of 30 percent or more that you cite in your paper, right?

A. So you are asking if 30 is different than 5, and the answer is yes, 30 is different than 5.

Q. And you believe that you reported objectively on the success rates with colporrhaphy?

A. Yes. I think this paper, actually, this later information actually is somewhat of an anomaly; and I think most -- most papers and again, there is, you know, lots of data and lots of studies that aren't cited here, would suggest that the number is higher than 5 percent. And again, there is going to be a variety based on the paper.

Q. Okay. Well, let's go to one of the other papers that you cited and Fed Ex'd. I thought this one was apparently really important, and I just have two copies of this one, I'm sorry to say.

We will mark that as the next exhibit, 9, and you are familiar with this paper because you cite it in your paper, in your report, right?

A. Yeah. Peter --

MR. MORIARTY: It's so big you can hardly miss it.

MS. THOMPSON: The first paper was that -- I have two of these that are large size. The first one was from Duke. I thought they just thought it was from Duke that it was important.

THE WITNESS: These guys work with us. They are part of the University of Chicago now, Peter Sand and Roger Goldberg and Janet Tomezsko.

(Bales Exhibit 9 was marked for identification.)

BY MS. THOMPSON:

Q. I actually want to turn your attention to that discussion of this paper --

A. Okay.

Q. -- by Dr. Shull. Do you know Dr. Shull?

A. I don't.

Q. Have you seen Dr. Shull cited in Ethicon

documents frequently?

A. I think I'm familiar with that name. He is not a urologist; he is a urogynecologist. I think I have seen the name.

Q. And have you looked at his comment regarding Dr. Sand's paper, you will see that, I'm going to read to you from the comment, "They knew from their own experience as well as the experience of other surgeons that the use of nonabsorbable mesh is associated with an unacceptably high rate of complications. This is not surprising when one considers operating in a clean-contaminated field, the vagina."

And this paper used an absorbable mesh, correct, not polypropylene?

MR. MORIARTY: Objection, form. Go ahead.

A. Yeah, I guess I'm just -- you just read --

Q. Did this paper use absorbable mesh?

A. Yes, correct.

Q. Okay. And did Dr. Shull describe -- well, I'm going to read you something. Tell me if this is what the paper states. "In our most recent

series of over 300 women" --

MR. MORIARTY: I'm sorry. Can you please tell us what you are reading from?

MS. THOMPSON: Several factors are related to long-term outcome.

MR. MORIARTY: We need to know where you are reading from.

MS. THOMPSON: I'm telling you. In the comments section it says several factors are related to long-term outcome, and I'm reading from number one.

BY MS. THOMPSON:

Q. "In our most recent series of greater than 300 women in whom we specifically repaired the transverse portion of the pubocervical fascia, along with other defects, the rate of anterior compartment persistence or recurrence was 7 percent for prolapse halfway to the hymen and 2 percent for prolapse to the hymen. We used no mesh."

You will agree with me that a success rate of 7 percent halfway to the hymen and 2 percent for prolapse to the hymen with a native tissue repair is significantly less than the 30 percent that you cited in your expert report,

correct?

MR. MORIARTY: Objection, form.

A. I think 30 percent is a more accurate representation of what the experience is nationwide for sure, as you just read.

Dr. Shull is a very accomplished urogynecologist who I don't know personally, but he is citing his own work, and he obviously gets excellent results with his native tissue repair.

I'm not sure how long these patients were followed, but he cites 7 percent in his experience, and 7 percent is a lower number than 30 percent.

MS. THOMPSON: I've just handed another paper. Would you mark this as Exhibit No. 9.

MR. MORIARTY: 10.

(Bales Exhibit 10 was marked for identification.)

BY MS. THOMPSON:

Q. Dr. Bales, are you familiar with Exhibit 10, a paper by Funk and Visco?

A. Yes.

Q. And this paper looked at 27,809 anterior

prolapse surgeries. The 5-year risk of surgery for recurrent prolapse was similar between vaginal mesh and native tissue groups with 10.4 percent recurrent with mesh and 9.3 recurrent with native tissue. You will agree that those numbers are significantly less than the 30 percent that you cited in your expert report, correct?

A. Yes.

Q. And that there was -- in this paper of 27,000-plus patients, there was no difference between mesh and native tissue repairs, correct?

A. Yes, it looks like they are, right, essentially similar.

MS. THOMPSON: And Exhibit No. 11.

(Bales Exhibit 11 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper by Dr. Oversand?

A. Yes.

Q. And Dr. Oversand had a satisfaction rate of 94 percent of patients with native tissue anterior repairs and a 5-year reoperation rate of 2.6 percent in one group and 8.9 percent in the

other group and concluded that POP surgery using native tissue repair entails low reoperation rates with excellent subjective and objective results and should be the primary -- should be the first choice in treating primary POP providing use of adequate surgical technique as was published in 2013.

That's certainly different from what you cited in your expert report, correct?

MR. MORIARTY: Objection, form.

A. Again, the numbers are lower in this paper in terms of the recurrence rates, yes.

MS. THOMPSON: And Exhibit No. 12.

(Bales Exhibit 12 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper, Dr. Bales?

A. Yes.

Q. And this is the three-year followup on Dr. Iglesia's original Prolift study, correct?

A. Yes. I'm just trying to see if they are all Prolift people, to make sure on the methods.

Yes, okay.

Q. And you are aware that this study was

halted prematurely because of 15.6 percent mesh erosion rate which exceeded their predetermined limit, correct?

A. Yes, it is prematurely halted.

Q. And -- but they continued to follow the patients for efficacy, correct?

And these authors concluded that there was no difference in three-year cure rates when comparing patients undergoing traditional vaginal prolapse surgery without mesh with those undergoing vaginal colpopexy repair with mesh, correct?

A. Right. You can read their conclusion. They saw no difference.

Q. And this paper wasn't included in your expert report, was it?

A. I don't think so.

Q. And it is still your opinion that colporrhaphy has a recurrence of over 30 percent and that mesh repairs are preferable?

MR. MORIARTY: Objection, form.

A. It's my opinion that, yeah, anterior recurrence rates are as high as 30 percent.

Q. Or you said 30 percent or more, not as high as 30 percent.

A. As high as 30 percent or more than 30 percent.

Q. So your opinion is the recurrence, high rates of recurrence of 30 percent or more with colporrhaphy?

A. Yes. If you follow patients long enough, yes, I believe that's an accurate statement, even though there is certainly papers that we can tease out of the literature, as we are doing, that show the recurrence rate is lower.

Q. But you didn't mention any of those articles in your expert report, correct?

A. The bibliography on the expert report, as you've stated now several times, did not include every single paper in the literature.

Q. And I'm actually using many of your papers that you just took the information that was favorable to your opinions, correct?

A. I appreciate that very much, counsel.

Q. Correct?

A. Correct.

MS. THOMPSON: Another big one, Exhibit 13.

(Bales Exhibit 13 was marked for

hour and a half. Ready for a break?

MS. THOMPSON: Sure, take a break.

(Recess taken, 9:32 - 9:41 a.m.)

MS. THOMPSON: Back on.

BY MS. THOMPSON:

Q. I had asked earlier, Dr. Bales, your opinion that the only unique risk is mesh exposure and erosion, and for that opinion you cited the Abed paper from 2011, correct?

A. I did.

MS. THOMPSON: And we will mark this as Exhibit 15.

(Bales Exhibit 15 was marked for identification.)

BY MS. THOMPSON:

Q. And this paper is titled "Incidence and management of graft erosion, wound granulation and dyspareunia following vaginal prolapse repair with graft materials: a systematic review."

Why did you not include the dyspareunia that's discussed in this paper when you cited it as your support for the only unique risk with Prolift or Gynemesh PS is mesh exposure and erosion?

A. Well, that sentence is as stated. I'm

just discussing the unique risk associated with having the mesh, and you know, in other areas we talk about dyspareunia rates and the first paragraph discusses dyspareunia rates and such. So, I didn't include every part of this paper.

Q. Does this paper state that the only unique risk with Prolift or Gynemesh PS is exposure and erosion?

A. I don't know if that exact verbiage is used in this paper. I would have to refresh my memory.

Q. Well, obviously it wouldn't because it discusses graft erosion, wound granulation and dyspareunia following prolapse with graft materials, right?

A. Right, and my point in writing my report is that those other type complications can be seen with or without the presence of mesh, which is one of the reasons. Again, we describe the unique risk being the presence of the mesh and the exposure and the erosion, so I guess just to clarify that.

Q. But you have already said that the rates, the incidence, the severity, the permanence and responsiveness to treatment are all important

when you are talking about adverse events or complications, right?

A. Yes, it's all important.

Q. And at least in this review, the dyspareunia rate associated with graft materials was 9.1 percent, correct?

A. That's correct.

Q. We were talking also about Jacquetin, who is an Ethicon consultant, and I will represent to you that he is a patent holder on Prolift.

MR. MORIARTY: Is this one for me or is this the only one?

MS. THOMPSON: Some of these I just have two copies of, I apologize.

MR. MORIARTY: Are you marking it?

MS. THOMPSON: Yeah, I will go ahead and mark it.

THE WITNESS: So I guess we are up to 16.

(Bales Exhibit 16 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper, Doctor --

A. Yes.

Q. -- Bales? And actually, which did I give you?

A. You have too many papers.

Q. I do. I actually meant to give you a different one, but we will go ahead and talk about this one. This is a paper, the 2013 --

A. 2009.

Q. This is the 2010 Jacquetin paper, the three-year followup.

And you will agree with me, in this paper the anatomical failure rate was 20 percent at three years, correct, in the results section?

A. Correct. You are reading right from the paper.

Q. Yep. And Dr. Jacquetin found that, listing results of the abstract summary, correct, listed that or stated that a significant number of patients, 41 percent, ceased sexual activity by three years, correct?

A. That's what his results were.

Q. And that de novo dyspareunia was reported by 8.8 percent, correct?

A. Correct.

Q. And that would be consistent also with the paper we just looked at previously, at the Abed paper, correct?

MR. MORIARTY: Objection. Are you just talking about the dyspareunia rate?

MS. THOMPSON: Just the dyspareunia. Sorry.

A. Yes.

Q. If we go to the Jacquetin 2013 paper -- we will mark this one too, 17. I think you are familiar with this one because it is cited in your expert report, correct?

A. Correct.

(Bales Exhibit 17 was marked for identification.)

BY MS. THOMPSON:

Q. And this Jacquetin paper with the followup of the TVM, total transvaginal mesh series, this is the one that your chart was derived from, correct?

A. Yes.

Q. And in this paper, in the results section of the abstract, Dr. Jacquetin reports 16 percent with mesh exposure for which 8 resections

needed to be performed, 7 exposures still ongoing at the 5-year endpoint, all asymptomatic, correct? I'm reading that correctly?

A. You are reading that correctly, yes.

Q. And only 33 out of 61, 54 percent, sexually active patients at baseline remained so at 5 years in his study, correct?

A. That's correct.

Q. And de novo dyspareunia was reported by 10 percent, correct?

A. That's correct.

Q. And you are aware that Jacquetin also published a paper based on the experience titled "Complications of Vaginal Mesh"?

A. Do you have it? Did you want to go over it?

Q. I need a helper.

A. Maybe this young fella.

MS. THOMPSON: It is just a short paper. I do have one additional copy, and we will mark that as Exhibit 18.

(Bales Exhibit 18 was marked for identification.)

Q. And he lists retractions, correct?
A. That's correct. We are reading, yes, those are the three things.
Q. And he describes the average shrinking of 25 to 30 percent in experimental surgery, and it may reach 40 percent of the initial surface of the implant in patients after surgery.
MR. MORIARTY: Is that a question?
Q. And therefore, many surgeons will use large implants to cover defects and anticipate scarring, shrinkage and puckering. Is that what Dr. Jacquetin describes in this paper?
MR. MORIARTY: Objection, form.
Q. Did I read it correctly?
A. I think that bullet point you read exactly, so that's what he has written here, yeah.
Q. And we will talk about your opinions on shrinkage in a minute, but at least Dr. Jacquetin listed that retraction as a complication of the mesh devices he studied, correct?
A. Sure, and you left out -- right, and he describes on a rat's abdominal wall and then he is guesstimating based -- he says it may reach 40 percent on patients. So, it sounds like at

least on the experimental side it's on the rat's abdominal wall, but you read the rest of the sentence accurately.

Q. So, you think when he says -- sorry. So, you think when he says, therefore, many surgeons will use large implants to cover defects and anticipate scarring, shrinkage and puckering he is talking about rat surgeons?

MR. MORIARTY: Objection, form.

MS. THOMPSON: Well, I'm just asking if that's what he meant, what he said.

MR. MORIARTY: You asked him if you read that exactly, and you didn't. You skipped the part about the rats, so he was just pointing out what you skipped.

MS. THOMPSON: I don't think I did.

MR. MORIARTY: That's why I objected to form. You skipped the part about the rats.

MS. THOMPSON: Well, I didn't intend to skip.

BY MS. THOMPSON:

Q. You don't think the second sentence is applying to rats, do you, Dr. Bales?

A. Well, the second sentence specifically

says patients; the first sentence definitely says rats. So, I guess that was the only clarification.

Q. So you think the 40 percent would refer to patients, human patients, right?

A. Well, again, I mean, he is not citing any specific study here. It sounds like he is surmising it may reach. I don't --

Q. But he is talking about humans, right?

A. He says in patients, so I would assume that means patients.

Q. And when he says many surgeons will use large implants to cover defect and anticipate scarring, shrinking and puckering, he is talking about human patients also; agree?

A. I suspect, although again, it's a very general statement, and I'm not sure which surgeons he is referring to or anything, how large. I mean, it's just kind of a very general statement. I imagine he is referring to surgeons operating on humans. I don't want to over-infer.

Q. Okay. I want appreciate that.

(Mr. Jake Plattenberger entered the deposition proceedings.)

MR. MORIARTY: Can we help you?

thorough physical exam. There is no urologic cause for dyspareunia. I mean, bladder pain and dyspareunia are slightly distinct, right, so dyspareunia --

Q. Or postoperative urologic surgery?

A. Correct.

Q. So, your opinion that the quality of dyspareunia and vaginal pain that occurs after mesh surgery is no different from that that can occur with other prolapse surgery?

A. Yes. It may not be any different at all.

Q. And you are ignoring the dozens of articles that would say something differently, correct?

MR. MORIARTY: Objection, form. Go ahead. It's argumentative.

A. I'm not sure they say anything a whole lot differently. There is papers that cite pain and dyspareunia after any type of vaginal surgeries and stuff; and certainly among those, as you stated earlier, are papers now looking at experiences with vaginal mesh procedures.

Q. Can you cite any paper that would

support your opinion that the pain associated with vaginal mesh is no different -- and we are considering all the factors, not that just that it occurs. Can you cite any paper that says that pain that occurs after mesh procedure is no different from that occurring with any other native tissue repairs?

A. I'm not sure there has been a comparative study, so I can't say that.

Q. It doesn't even have to be a comparative study. Has anybody offered an opinion that the mesh pain after mesh surgery is no different when you consider all the factors that we have talked about, the native tissue repairs?

MR. MORIARTY: Objection. Go ahead.

A. So, if I see a patient who has vaginal pain and fibromyalgias and says she can't get near her husband and she is on the verge of divorce and she is coming to see me because she was told I'm a pelvic floor reconstructive guy and what can I offer her and that woman has never had vaginal mesh surgery, any surgery, and she has horrific dyspareunia that's affecting her marriage, that woman's dyspareunia is no different than a patient

"The authors conclude that the risk/benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that in women with higher risk of recurrence the benefits may outweigh the risk, there is currently no evidence to support this position."

Did I read that correctly?

A. You read it perfectly.

Q. And in the last paragraph, "In 2011, many transvaginal permanent meshes were voluntarily withdrawn from the market and the newer lightweight transvaginal permanent meshes still available had not been evaluated within an RCT. In the meantime, these newer transvaginal meshes should be utilized under the discretion of the ethics committee."

Did I read that correctly?

A. Yes. You read it fine.

Q. In 2016 the authors of the Cochrane study, with Prolift having been on the market for 11 years and Gynemesh on the market for 16 years, are stating that these meshes should only be utilized under the discretion of an ethics committee, correct?

BY MS. THOMPSON:

Q. Are you familiar with this paper titled "Vaginal Mesh Contraction, Definition, Clinical Presentation and Management"?

A. Yes.

Q. And one of the two authors of this paper is also the author of the Cochrane reviews that you cited in your paper as well?

A. Maher.

Q. Maher. Is it your opinion that vaginal mesh contraction is not unique to vaginal mesh devices?

A. It is not -- say that again.

Q. You've given the opinion that the only complication unique to vaginal mesh devices is exposure and erosion, and I'm asking you is vaginal mesh contraction not unique to vaginal mesh devices?

A. I guess anything having to do with the mesh itself is unique to the mesh. We could argue about the extent of contracture, if you will. But if the mesh changes at all, it's only going to change if the mesh is present. So, again, I'm not sure that's a complication, but it's a behavior of

the mesh. Maybe that's more accurate.

Q. Vaginal mesh contraction characterized by severe vaginal pain, aggravated by movement, dyspareunia in all sexually active women and focal tenderness over contracted portions of the mesh on vaginal examination, commonly involving the lateral fixation arms, you have a question about whether that's a complication or not?

A. I don't have a question. If the pain exists, I have a question how much is specifically due to contracture, which is what you were just talking about.

Q. Well, these authors are reporting vaginal mesh contraction. Do you question their report?

A. I mean, their report is their report.

Q. And it certainly wasn't included in your expert report, was it?

A. It was not.

Q. Vaginal mesh contraction characterized by severe vaginal pain, dyspareunia in all women and focal tenderness over contraction. In fact, you say it's not even established that mesh contracts to any clinical significant degree;

correct?

A. That's what I said.

Q. You certainly consider vaginal mesh contraction a significant clinical condition, correct?

MR. MORIARTY: Objection. Go ahead.

A. I guess that we can argue about how much and how relevant contracture, how much it occurs, how well it's measured, and if that truly is clinically significant. Certainly these authors feel that they felt some of the pain that they are seeing is related to contracture.

Q. And you are aware that there are dozens, literally, of articles describing mesh contracture and the clinical symptoms, primarily pain, associated with it, correct?

A. I'm aware that both those things exist, and I'm certainly aware that mesh contractures occur, just like mesh contractures occur in inguinal hernias and ventral hernia and whatever, yes.

Q. Okay. We are talking about vaginal mesh contractions, right?

A. Yes, and I'm aware that they contract a

A. I'm not convinced that in all those patients it's simply -- it's as simple as saying a little contraction occurred, and that's what's causing all the pain. I think that it's not very well defined. That's my opinion.

Q. Okay. The one paper you did out of the literally dozens of papers that discussed this, including the FDA, as a clinically significant condition that is unique to mesh, the one paper you selected to include in your expert report is Dietz. My question is --

A. So you are happy with this one, that I included this one?

Q. Oh, let's talk about this one.

A. Okay. Please.

Q. Did you find this paper on your own or were --

MR. MORIARTY: Is this marked?

MS. THOMPSON: Let's mark that as the exhibit next.

(Bales Exhibit 24 was marked for identification.)

BY MS. THOMPSON:

Q. My question, first of all, is this a

paper you found on your own literature search, or was this something that was furnished to you by defense counsel?

A. I don't recall. I think I found it on my own.

Q. And this is the one you chose out of dozens, if not hundreds, of articles that discuss mesh shrinkage, contraction, retraction and the clinical significance, correct?

MR. MORIARTY: Objection, form.

A. This is one that's cited in my Herrera report.

Q. Let's look at this report from 2011. You are aware that Dr. Dietz is a consultant for mesh manufacturers, correct?

A. Yes. Well, I'm just reading it. Actually, I didn't remember that, but I'm reading underneath on the first page here. It says he has acted as a consultant for various vendors, so yes, I guess he is.

Q. And Dr. Dietz used translabial ultrasound in this study, correct?

A. Correct.

Q. Wouldn't that transvaginal ultrasound be

more accurate in assessing mesh in the pelvic floor?

A. You know, I don't do translabial ultrasounds, so I'm not sure how well it penetrates to be able to assess it. I'm assuming that whether it is translabial or transvaginal, they were able to get dimensions, but I don't know enough about translabial ultrasound.

Q. Aren't most of the papers that you've seen or have you seen any looking at ultrasound to assess mesh shrinkage using transvaginal ultrasound?

A. Yes. Loyola has published some papers here in Chicago, Dr. Mueller. So, yes, I'm aware of that technique, and there has been some reports on that.

Q. And Dr. Dietz did the first scan in his paper at a minimum of three months, so the first scan was done three months following the placement of the surgery -- the placement of the mesh, correct?

A. It looks like the study design, it was between 3 and 52 months.

Q. And it's true that folding, wrinkling,

Systems product. This isn't even an Ethicon product. Sure, I would believe this. They describe that. I guess they measured it, and it's 5 by 3.7 centimeters.

Q. Well, you chose the paper about Perigee, not me, right?

MR. MORIARTY: Objection, argumentative. What does that have to do with anything?

MS. THOMPSON: Well, he was questioning that it wasn't even an Ethicon product, and I was just bringing to his attention that he was the one that picked a non-Ethicon paper when there were other Ethicon papers he could have chosen.

MR. MORIARTY: I thought you were asking about the dimensions of the Perigee.

MS. THOMPSON: I am.

BY MS. THOMPSON:

Q. Now, if you go to the chart on Page e3 giving the dimensions, the lower mesh margin.

A. Table 1 or Table 2?

Q. Table 1. And the mesh link, those measurements are significantly different, smaller

a few minutes to read over their methods. I'm happy to do that.

Q. It's only a four-page paper, right?

A. You are the one who says we don't have time. I have plenty of time.

Q. Let's go ahead and look at some shrinkage information on Ethicon products. Okay?

A. Okay.

MS. THOMPSON: We will mark this as 25.

(Bales Exhibit 25 was marked for identification.)

BY MS. THOMPSON:

Q. And I'm looking specifically at the abstract 157 by the authors Letouzey and De Tayrac, among others. Are you aware that these authors are part of the TVM group in France?

A. Yeah. I think I recognize the Levaillant. I'm not perhaps pronouncing that, the Levaillant name.

Q. And this study actually used Gynemesh, correct?

A. Yes.

Q. And it was placed under the bladder in a

tension-free procedure, correct?

A. Correct.

Q. And the results of this study showed that ultrasound evaluation reconstruction has been shown to -- a typo -- has been showed a mean contraction of 30 percent, 65 percent, 85 percent at a mean followup of 3 years, 6 years and 8 years respectively, correct? Did I read that correctly?

A. Yes.

Q. 85 percent at 8 years is certainly not any clinically significant degree, as you stated in your report, is it?

A. Well, you know, it is interesting. If we read just a little further, there was no significant correlation between mesh position and clinical outcomes. So actually, it seems to indicate by their results that while it's contracted, it hasn't affected outcomes. So, I guess it's not clinically significant if you believe this one abstract.

Q. Did the mesh shrink in this abstract by Dr. Tayrac?

A. Well, according to the ultrasound measurements, you just stated the numbers,

30 percent, 65 percent, et cetera.

MS. THOMPSON: We will mark this as Exhibit 26.

(Bales Exhibit 26 was marked for identification.)

BY MS. THOMPSON:

Q. Did you look at any Ethicon documents regarding mesh shrinkage and the clinical significance?

A. Yes, I looked at some documents.

Q. Did you look at this document that I just marked as Exhibit 26 that says, "Mesh shrinkage: How to assess, how to prevent, how to manage?" by authors Velemir, Fatton and Jacquetin, also part of the TVM investigating group on Gynemesh and Prolift? Have you seen this document?

A. I may have.

Q. Go ahead and look through it, if you would like, and let me know when you are ready.

A. Well, I don't know what to be ready for, so I'm not sure if I'm ready.

Q. I want to ask you some questions, but I will direct you to the right place.

A. When you don't know what to expect, it

is hard to know if you are ready.

Q. Fair enough. And this entire document, it looks like it was a workshop, is postoperative specific complications following transvaginal mesh repair of pelvic organ prolapse, etiology, prevention and management; and the entire -- I don't know how many pages it is but it's long -- is about mesh shrinkage, correct?

A. I don't know. I didn't have time to go through every single page just now.

Q. Well, the title is "Mesh Shrinkage," so you can probably assume that the document is about mesh shrinkage, right?

MR. MORIARTY: Your question was whether every page of the thing was about mesh shrinkage, so don't get frustrated by his answer when he hasn't assessed because I'm looking at the third page and it isn't about shrinkage. So, I understand your frustration, but if your question is going to be that way...

BY MS. THOMPSON:

Q. Okay. Let's just go through several of these pages. All right. It gives a definition of

mesh shrinkage on page -- the second page, reduction of the mesh area after tissue incorporation, correct?

A. That's what it lists as the definition.

Q. And it also says it's often associated with mesh thickening and folding, correct?

A. That's the third bullet point there, yes, often associated with mesh thickening and folding.

Q. Would you disagree that mesh shrinkage is often associated with mesh thickening and folding?

A. That hasn't been my experience.

Q. So you would disagree with Ethicon that mesh shrinkage is often associated with mesh thickening and folding?

MR. MORIARTY: Objection, objection to form.

Q. You can answer.

A. It hasn't been my experience that I have seen in my own patients a lot of mesh thickening and folding, so I don't know who I'm disagreeing with, but you asked me what my opinion is, and I haven't seen that.

Q. Would you agree that mesh shrinkage is a phenomenon experienced by abdominal surgeons?

A. When using mesh for what procedures? So use mesh for ventral hernias, for instance, or what specifically?

Q. I'm just reading. Do you agree with the statement from Drs. Velemir, Fatton and Jacquetin of the TVM group in France investigating Gynemesh and Prolift that mesh shrinkage is a phenomenon experienced by abdominal surgeons?

A. Well, I guess I don't disagree, I don't agree. I'm not sure what they are referring to there, so I don't want to just --

Q. So you can't answer that question?

A. Again, let me finish. As a blanket statement I just want to say I agree. I'm just not sure what they are referring to.

Q. And do you agree with the statement that mesh shrinkage is a phenomenon which has become a rising concern in urogynecology since the widespread use of vaginal mesh?

A. I think it's a concern for urogynecologists, urologists. Anybody who is using vaginal mesh, it would be a concern.

statement is "Mesh shrinkage may be associated with," bullet points, "stiffness/tenderness at vaginal examination." Would you agree with that?

MR. MORIARTY: Objection, form. Go ahead.

Q. Would you agree with mesh shrinkage may be associated with stiffness and tenderness at vaginal examination?

MR. MORIARTY: Same objection.

A. I guess I would agree. May be associated, I guess I could agree with that statement.

Q. Would you agree that mesh shrinkage may be associated with discomfort, pain during intercourse?

MR. MORIARTY: Same objection.

A. I guess I would just underscore again that I don't know how easy it is to determine whether mesh shrinkage is what's causing discomfort and pain after intercourse, so that's why. So, I guess may, may be associated, sure. I guess I could on balance say that's okay.

Q. And you certainly agree that there are many papers where the authors are able to make the

connection between the shrinkage, retraction, contraction and pain; you just are not able to, correct?

MR. MORIARTY: Objection, form. Go ahead.

A. Yes, I'm not able to.

Q. Do you agree with the statement mesh shrinkage may be associated with pelvic pain?

MR. MORIARTY: Same objection.

A. I think it was the same thing we said before. There is -- when patients have pain, specifically the mesh being possibly shrinking or is shrinking, is that the cause of the pain, I guess it can be hard to say. So, that's my only concerning about making that blanket statement.

Q. Do you agree or disagree with the statement mesh shrinkage may be associated with urinary or defecatory dysfunctions?

MR. MORIARTY: Same objection.

A. I -- yeah, I guess I'm not sure if the mesh -- yeah, I guess I'm not prepared to say mesh shrinkage causes urinary or defecatory dysfunction, so no.

Q. Do you disagree or agree with the